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Dear Mr. Jackson:

I would like to **comment on the Advanced Notice of Proposed Rule Making (69 Feb. Reg. 70197)**. The question posed is whether excluding venture capital companies from the SBA's affiliation rules would help small businesses interested in participating in the SBIR program.

It is my opinions that the SBA's proposal to relax the affiliation rules is not likely to have a significant impact on small biotechnology companies – which are exactly the type of companies that are meant to benefit from the SBIR program. The primary reason that many biotech firms have been excluded from participating in the SBIR program is not because they are being considered “affiliates” of large joint venture firms (the problem this proposed rule would address) but rather, the obstacle has been that the SBA excludes firms that are not majority owned by “individuals.” Most biotechnology firms in the United States receive funding from multiple venture capital sources, therefore these businesses are not majority-owned by individual people and are not eligible to participate under the SBA's current requirements.

The biotechnology industry is unique in that it takes a large amount of capital to bring a product to market; therefore, most small firms need to seek out venture capital funding at the early stages of development. The cost of developing new technologies is simply too high (usually hundreds of millions of dollars) to be sustained by individual investors.

Acorda Therapeutics exemplifies Congress' original intent with respect to the SBIR program. We are a ten-year-old biotechnology company developing therapies for people with spinal cord injury, multiple sclerosis, and other nervous system conditions. The company is based in Westchester County, New York, and currently employs 59 associates, most of whom are highly educated and skilled. Over the years, our company has applied for 25 SBIR grants and received several Phase 1 SBIR and SSTR grants and a Phase 2 STTR (Small Business Technology Transfer) grant from the NIH. These grants have been critical to our ability to develop technologies that have the potential to benefit people living with spinal cord injury and multiple sclerosis. We have been able to leverage the dollars we received from the SBIR program to develop our technologies at an early stage before they would have attracted the interest of the VCs. The combination of SBIR grants and VC support were critical to bringing our lead drug product, Fampridine-SR, into the clinic. Fampridine-SR is a novel therapy that has been shown in clinical trials to restore some function to people with multiple sclerosis and spinal cord injury.

The Biotechnology Industry Organization (BIO), of which Acorda is a member, has proposed to SBA and Members of Congress that the definition of “small business” be clarified to include those companies that are owned by one or more venture capital companies. We agree with this recommendation, as it is the only way to ensure that companies that are intended to benefit from the SBIR program have equal opportunity to apply for and benefit from these grants.

Sincerely,

Ron Cohen, M.D.  
President and CEO